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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,728	01/17/2002	John Victor Lamont	111723	2576

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,728	LAMONT ET AL.	
	Examin r	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 July 2003 has been entered.

Status of the Claims

2. This action is in response to papers filed 28 July 2003 in which Claim 1 was amended and Claims 15 and 16 were canceled. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 27 March 2003 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1 and 3-14 are under prosecution.

Specification

3. The amendment filed 28 July 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendments to Claim 1 add the limitation "a first molecule located on the solid support at a known position **within** the array". While the originally filed specification teaches the first molecule is located in "should be located at a pre-defined position on each biochip. For example, a reference molecule may be located in one or more corners of the biochip"(page 4, lines 4-6) and further teaches the first molecule is located "in or near a corner of the biochip array" (page 5, lines 34-45). The originally filed specification does not teach the first molecule located within the array. Therefore, the newly added recitation introduces new matter into the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 and 3-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation "a first molecule located on the solid support at a known position **within** the array" is added to the newly amended independent Claim 1 (from which Claims 3-14 depend. However, the specification fails to define or provide any disclosure to support such claim recitation.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 4-10 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Fiekowsky et al (U.S. Patent No. 6,090,555, issued 18 July 2000).

Regarding Claim 1, Fiekowsky et al disclose a method for imaging an array of discrete reaction sites on the surface of a solid support to detect the presence of molecules on the array the method comprising imaging the array and detecting a signal from a first molecule located on the solid support at a known position within the array (i.e. control probes, Column 7, lines 43-63), by reference to the first molecule aligning an individual inspection window in registration with each discrete reaction site and determining the amount of detectable signal (measure fluorescence intensity) in each window to thereby detect the presence of molecules (Column 5, lines 5-28; Column 6, line 59-Column 7, line 67; and Column 10, lines 6-38).

Regarding Claim 4, Fiekowsky et al disclose the method wherein after detecting a first molecule the first inspection window is repositioned so that one or more of the discrete reaction sites are also located within the window detecting the one or more sites and by reference to the first molecule aligning a further inspection window (Column 9, line 30-Column 10, line 39 and Fig. 12-13).

Regarding Claim 5, Fiekowsky et al disclose the method wherein the array of reaction sites defines a corner within which the first molecule is located (Column 7, lines 55-60 and Fig. 9A).

Regarding Claim 6, Fiekowsky et al disclose the method wherein step (i) further comprises detecting a second molecule located on the solid support at a known position with respect to the array and aligning the inspection windows by reference to both first and second windows (i.e. at each corner, Column 7, lines 59-60)

Regarding Claim 7, Fiekowsky et al disclose the method wherein the imaging is carried out by detecting emitted radiation (Column 7, lines 1-16).

Regarding Claim 8, Fiekowsky et al disclose the method wherein the radiation is chemiluminescent, bioluminescent or fluorescent (Column 4, lines 7-17).

Regarding Claim 9, Fiekowsky et al disclose the method wherein the molecules of the array are capable of reacting with an analyte i.e. hybridize to (Column 6, lines 59-67).

Regarding Claim 10, Fiekowsky et al disclose the method wherein the molecules of the array are polynucleotides (Column 6, lines 59-67).

Regarding Claim 14, Fiekowsky et al disclose the method wherein the signal detection of step (i) must be above a pre-defined value in order to proceed i.e. brightness (Column 8, lines 3-32 and Fig. 8).

8. Claims 1 and 4-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Noblett (U.S. Patent No. 6,362,004, filed 9 November 1999).

Regarding Claim 1, Noblett discloses a method of imaging an array of discrete reaction sites on the surface of a solid support to detect the presence of molecules on the array, said molecules being detectably labeled (Column 6, lines 64-67) comprising: imaging the array and detecting a signal representing a first molecule located on the solid support at a known position (i.e. fiducial mark, Column 5, lines 32-56) by reference to the first molecule aligning inspection windows in registration with the discrete reaction sites (Column 3, lines 32-35) and determining the amount of detectable signal in each window (Column 3, lines 24-35; Column

7, lines 21-67 and Claims 13-16) wherein detection of the first molecule is carried out by aligning a first inspection window within a region of the support that includes the first molecule and searching (scanning) within the window for an image of the first molecule (Column 7, line 21-Column 8, line 4).

Regarding Claim 4, Noblett discloses the method wherein after detecting the first molecule, the first inspection window is repositioned so that one or more reaction sites is located within the window, detecting the one or more sites and by reference to the first molecule, aligning a further inspection window (Column 7, line 61-Column 8, line 4 and Claim 15).

Regarding Claim 5, Noblett discloses the method wherein the array of reaction sites defines a corner within which the first molecule is located (Column 7, line 21-Column 8, line 4 and Fig. 2 & 7).

Regarding Claim 6, Noblett discloses the method further comprising detecting a second molecule (i.e. fiducial) on the solid support located at a known position and aligning the inspection windows by reference to both first and second molecules (Column 7, lines 61-66).

Regarding Claim 7, Noblett discloses the method wherein imagining is carried out by detecting emitted radiation (Column 7, lines 31-43 and Claim 13).

Regarding Claim 8, Noblett discloses the method wherein the radiation is fluorescent (Column 4, lines 35-49 and Claim 13).

Regarding Claim 9, Noblett discloses the method wherein the molecules of the array are capable of reacting with an analyte i.e. genetic material (Column 3, lines 50-53 and Claims 3-4).

Regarding Claim 10, Noblett discloses the method wherein the molecules of the array are polynucleotides i.e. genetic probe material (Column 3, lines 50-53 and Claims 3-4).

Respons to Argument

9. Applicant argues Noblett does not disclose the instantly claimed method because the fiducial marks of Noblett are not within the actual array of reaction sites but instead positioned

at separate and distinct locations away from the array. The argument has been considered but is not found persuasive because while Noblett does not specifically teach the fiducal marks are within the array, they do teach the fiducial is on the array as disclosed in the instant specification. For this reason, the rejection is maintained.

10. Claims 1, 3-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Juncosa et al (U.S. Patent No. 6,309,601 B1, filed 1 May 1997).

Regarding Claim 1, Juncosa et al disclose a method of imaging molecules contained in an array of discrete reaction sites on the surface of a solid support to detect the presence of molecules on the array, said molecules being detectably labeled (Column 5, lines 43-51) comprising: imaging the array and detecting a first molecule located on the solid support at a known position by reference to the first molecule aligning inspection windows in registration with the discrete reaction sites and determining the amount of detectable signal in each window (Column 4, line 48-Column 5, line 2 and Column 10, line 41-Column 11, line 10) wherein detection of the first molecule is carried out by aligning a first inspection window within a region of the support that includes the first molecule and searching within the window for an image of the first molecule (Column 4, line 48-Column 5, line 2 and Column 10, line 41-Column 11, line 10).

Regarding Claim 3, Juncosa et al disclose the method wherein the first inspection window defines a two-dimensional array of pixels and searching is carried out by scanning diagonally the array of pixels and determining values for the pixels (Column 4, line 48-Column 5, line 2 and Column 10, line 41-Column 11, line 10 and Fig. 6A).

Regarding Claim 4, Juncosa et al disclose the method wherein after detecting the first molecule, the first inspection window is repositioned so that one or more reaction sites is located within the window, detecting the one or more sites and by reference to the first molecule, aligning a further inspection window (Column 10, lines 41-60 and Column 12, lines 1-11).

Regarding Claim 5, Juncosa et al disclose the method wherein the array of reaction sites defines a corner within which the first molecule is located (Column 5, lines 38-51 and Fig 1).

Regarding Claim 6, Juncosa et al disclose the method further comprising detecting a second molecule (i.e. markers and/or fiducials) on the solid support located at a known position and aligning the inspection windows by reference to both first and second molecules (Column 11, lines 3-10).

Regarding Claim 7, Juncosa et al disclose the method wherein imagining is carried out by detecting emitted radiation (Column 5, lines 43-48).

Regarding Claim 8, Juncosa et al disclose the method wherein the radiation is fluorescent (Column 5, lines 43-48).

Regarding Claim 9, Juncosa et al disclose the method wherein the molecules of the array are capable of reacting with an analyte (Column 5, lines 43-48).

Regarding Claim 10, Juncosa et al disclose the method wherein the molecules of the array are polynucleotides, proteins, antibodies or organic compounds (Column 5, lines 43-48).

Regarding Claim 11, Juncosa et al disclose the method wherein the solid support is less than 1 cm^2 (Column 6, lines 21-23).

Response to Arguments

11. Applicant argues that Juncosa does not teach a first molecule located within the array and by reference to the first molecule aligning an individual inspection window in registration with each discrete reaction site. The argument has been considered but is not found

persuasive because Juncosa teaches alignment in registration with each site as claimed (Column 10, lines 45-66).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fiekowsky et al (U.S. Patent No. 6,090,555, issued 18 July 2000) in view of Juncosa et al (U.S. Patent No. 6,309,601, filed 1 May 1997).

Regarding Claim 3, Fiekowsky et al disclose a method for imaging an array of discrete reaction sites on the surface of a solid support to detect the presence of molecules on the array the method comprising imaging the array and detecting a signal from a first molecule located on the solid support at a known position within the array (i.e. control probes, Column 7, lines 43-63), by reference to the first molecule aligning an individual inspection window in registration with each discrete reaction site and determining the amount of detectable signal (measure fluorescence intensity) in each window to thereby detect the presence of molecules (Column 5, lines 5-28; Column 6, line 59-Column 7, line 67; and Column 10, lines 6-38) wherein the first inspection window defines a two-dimensional array of pixels and scanning is carried out by scanning the array of pixels and determining values for the pixels (Column 8, lines 33-58) wherein adjacent pixels are scanning e.g. 1-9 (Column 8, lines 50-58) which

clearly suggests that the pixels 1-9 are scanned in any order but they do not specifically teach diagonal scanning. However, diagonal scanning was known in the art at the time the claimed invention was made as taught by Juncosa (Fig. 6A) wherein it is taught that diagonal scanning is preferred (Column 11, lines 18-20). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the diagonal scanning of Juncosa et al to the scanning of pixels 1-9 of Fiekowsky et al based on their suggestion (Column 8, lines 50-58) and further based on the preferred teaching of Juncosa (Column 11, lines 18-20). As such one of ordinary skill would have been motivated to diagonally scan the array of Fiekowsky et al with a reasonable expectation of success.

14. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiekowsky et al (U.S. Patent No. 6,090,555, issued 18 July 2000) in view of Pirrung et al (U.S. Patent No. 5,143,854, issued 1 September 1992).

Regarding Claims 11-13, Fiekowsky et al disclose a method for imaging an array of discrete reaction sites on the surface of a solid support to detect the presence of molecules on the array the method comprising imaging the array and detecting a signal from a first molecule located on the solid support at a known position within the array (i.e. control probes, Column 7, lines 43-63), by reference to the first molecule aligning an individual inspection window in registration with each discrete reaction site and determining the amount of detectable signal (measure fluorescence intensity) in each window to thereby detect the presence of molecules (Column 5, lines 5-28; Column 6, line 59-Column 7, line 67; and Column 10, lines 6-38). Furthermore, they teach the array are made using VLSIPS™ technology as taught by Pirrung in U.S. Patent No. 5,143,854 (Column 1, lines 51-56 and Column 3, lines 26-29) but they do not

specifically teach the solid support is less than 1 cm^2 (Claim 11) wherein the solid support is ceramic, silicon or glass (Claim 12), or that the molecules are covalently attached to the solid support (Claim 13).

Pirrung et al teaches the VLSIPS™ technology wherein the support is less than 1 cm^2 (Column 15, lines 49-68 and Column 29, lines 28-42) wherein the solid support is made of silicon or glass (Column 11, lines 14-40) and wherein the molecules are covalently attached to the support (Column 3, lines 8-33 and Fig 14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the VLSIPS™ technology as taught by Pirrung to the substrate of Fiekowsky et al and to covalently attach the molecules to a substrate of less than 1 cm^2 and made of silicon or glass based because one of ordinary skill would have been motivated to use the preferred substrate for successful VLSIPS™ array production.

15. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Juncosa et al (U.S. Patent No. 6,309,601 B1, filed 1 May 1997) in view of Trulson et al (U.S. Patent No. 5,578,832, issued 26 November 1996).

Regarding Claim 12, Juncosa et al teach the method of imaging molecules contained in an array of discrete reaction sites on the surface of a solid support comprising: imaging the array and detecting a first molecule located on the solid support at a known position by reference to the first molecule aligning inspection windows in registration with the discrete reaction sites and determining the amount of detectable signal in each window (Column 4, line 48-Column 5, line 2 and Column 10, line 41-Column 11, line 10) wherein the array comprises a solid support (Column 5, lines 38-41) but they are silent regarding the composition of the

solid support. However, arrays on solid support comprising ceramic, glass or silicon were well known in the art at the time the claimed invention was made as taught by Trulson et al. Specifically, Trulson et al teach a similar method of imaging molecules contained in an array of discrete reaction sites on the surface of a solid support comprising: imaging the array and detecting a first molecule located on the solid support at a known position by reference to the and determining the amount of detectable signal in each window (Claims 14-22) wherein the solid support is glass, silicon or ceramic material (Column 4, lines 46-67 and Claim 22). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the routinely practiced glass, silicon or ceramic support of Trulson et al to the support of Juncosa et al based on the facts that they are routinely practiced in the art and are the preferred supports Trulson et al (Column 4, lines 66-67).

Regarding Claim 13, Juncosa et al teach the method wherein the molecules are on the surface of the array (Column 5, lines 38-50) but they are silent regarding covalent attachment to the surface. However, covalent attachment was well known and routinely practiced in the art at the time the claimed invention was made as taught by Trulson et al (Column 4, lines 18-20). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the covalently attached molecules of Trulson et al to the molecules of Juncosa et al and to covalently attach the molecules to thereby provide molecules which would remain stably attached under a wide range of experimental and environmental conditions thereby providing a multi-functional and/ or reusable array of molecules. The skilled practitioner in the art would have desired a multi-functional and/or reusable array for the obvious benefits of economy of manufacture and reagents.

Regarding Claim 14, Juncosa et al teach the method wherein the image generated is measured (Column 11, lines 11-48) but they do not teach the image must be above a pre-defined value. However, Trulson et al teach the similar method wherein the image generated must be above a pre-determined value i.e. peak (Claim 16). It would have been obvious to one

of ordinary skill in the art at the time the claimed invention was made to modify the image generation of Juncosa et al by determining a predetermined peak value of the image as taught by Trulson et al (Claim 16) thereby obtaining the image at its known peak value for the obvious benefits of optimizing signal detection to thereby maximize experimental results.

Response to Arguments

16. Applicant argues that Juncosa does not teach or describe the method of Claim 1 Trulson does not overcome the deficiencies of Juncosa and therefore Juncosa and Trulson alone or in combination do not render the invention of Claims 12-14 obvious. The argument has been considered but is not found persuasive for the reasons stated above in ¶ 7 regarding Trulson.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
November 10, 2003